APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN IDEC INC., BIOGEN IDEC MA INC. and GENZYME CORPORATION, Plaintiffs, v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, Defendant.	CIVIL ACTION No. 04-CV-12009-MLW

AMENDED COMPLAINT

Introduction

1. In 1983, more than twenty years ago, defendant The Trustees of Columbia University in the City of New York ("Columbia") obtained a patent on a recombinant DNA technology called "cotransformation," a process for inserting foreign DNA into a host cell to produce certain proteins. In 2002, two years after the expiration of that patent and two related patents, Columbia obtained yet another patent (the "'275 patent") on its cotransformation technology, and it maintains that the new patent will extend its patent monopoly until at least 2019.

2. When several licensees of Columbia's cotransformation patents sought recourse to the courts to challenge the validity and enforceability of the '275 patent, Columbia vexatiously manipulated the court system for the purpose of delaying judicial scrutiny of its new patent and imposing substantial burdens and costs on any licensees that challenged its patent. For example, in March 2004, after its licensees had sued for declaratory judgments that the new patent is

invalid and unenforceable, Columbia sought to punish them by terminating their licenses, ostensibly for failure to pay royalties due on the '275 patent. Columbia also sought to use the '275 patent, and to exploit the cost and uncertainty of litigation, by extracting settlements from various of its licensees. When Biogen Idec MA, Inc. and Genzyme Corporation moved to enjoin termination of their licenses, Columbia filed numerous papers opposing the motion and persuaded the Court to deny the motion, all at great cost to the plaintiffs. Less than three weeks after the Court denied their motion, Columbia reversed itself and asserted that the notices of termination were "ineffective." Columbia also filed a limited "covenant not to sue" certain parties on the '275 patent, in which it expressly excluded later developed products, as yet another tactic to escape judicial scrutiny of the patent. It then modified the scope of its covenant several times over the following weeks. In the meantime, Columbia continued to prosecute another pending patent application in the same patent family and also filed a broadening reissue application containing claims directed at its licensees' current commercial products. Plaintiffs bring this action for damages and declaratory relief to redress Columbia's illegitimate and costly attempts to enforce an invalid and unenforceable patent, its wrongful termination of plaintiffs' licenses, its breaches of their license agreements, and its abuse of the processes of this Court in furtherance of its unlawful patent licensing strategy.

3. Columbia's first cotransformation patent issued in August 1983. In 1987 and 1993, Columbia obtained two additional patents claiming substantially the same invention. All three patents originated from a single patent application filed by Columbia on February 25, 1980, and all three patents were based upon the same experimental research described in that application. Because the United States Patent and Trademark Office ("Patent Office") determined that the second and third of Columbia's cotransformation patents claimed obvious

variants of the first patent, and thus constituted impermissible "double-patenting," the Patent Office required Columbia to disclaim any rights in those patents extending beyond the expiration date of the first issued patent. As a result, all three patents expired the same day, August 16, 2000.

4. Columbia licensed its original cotransformation patents to over thirty biotechnology companies and received hundreds of millions of dollars in royalty payments, including significant sums it would not have received had it honored the "most favored licensee" clauses of its license agreements. In 2000, Columbia mounted a widely criticized campaign to obtain special legislation from Congress extending the term of its original cotransformation patent by fifteen months, the result of which would have been an estimated $100 million windfall for Columbia in the form of additional royalty payments from its licensees. Congress soundly rejected Columbia's effort. Accordingly, all three patents expired that year, and Columbia's cotransformation inventions entered the public domain.

5. Unbeknownst to Congress and the public, however, Columbia was simultaneously prosecuting still more patent applications on its cotransformation technology. Columbia filed these applications in 1995, but had delayed prosecuting them through a variety of dilatory tactics. When Columbia's lobbying effort failed, Columbia refocused its efforts on its still pending patent applications. Through this strategy, Columbia found an alternative means to extend the life of its patent monopoly, not just for the fifteen months Columbia had requested unsuccessfully from Congress, but for seventeen years. By misleading the Patent Office about the claim scope of its earlier cotransformation patents, Columbia obtained for itself on September 24, 2002 a **fourth** cotransformation patent, with a term extending all the way to 2019, based on the **same** research described in the **same** 1980 patent application that had given rise to

the first three cotransformation patents. Columbia's new patent is U.S. Patent No. 6,455,275 (the "'275 patent").

6. Columbia asserts that its new '275 patent is valid, enforceable and infringed. Because the '275 patent is invalid and unenforceable, as explained below, this Court should grant declaratory and injunctive relief preventing its enforcement. In addition, this Court should award damages, treble damages, and attorneys' fees as remedies for Columbia's improper actions in the Patent Office and this Court and for Columbia's breaches of its license agreements.

Parties

7. Plaintiff Biogen Idec Inc. ("Biogen Idec"), previously known as IDEC Pharmaceuticals Corporation, is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. On November 12, 2003, Bridges Merger Corporation, a wholly owned subsidiary of IDEC Pharmaceuticals Corporation, was merged with and into Biogen, Inc. with Biogen, Inc. continuing as the surviving corporation and a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. At the same time IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc. (referred to herein as "Biogen Idec") and Biogen, Inc. was renamed Biogen Idec MA, Inc. (referred to herein as "Biogen").

8. Biogen Idec developed RITUXAN® (rituximab), a leading cancer therapeutic that is approved to treat non-Hodgkin's lymphomas, and ZEVALIN® (ibritumomab tiuxetan), the first radioimmunotherapy approved for the treatment of cancer. Biogen Idec co-markets RITUXAN® with Genentech, Inc. Biogen Idec has never entered into a license agreement with Columbia with respect to Columbia's cotransformation technology.

9. Plaintiff Biogen Idec MA, Inc. ("Biogen"), previously known as Biogen Inc., is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Biogen has been engaged in biotechnology research for over twenty-five years. Its research led

to the development of AVONEX® (Interferon beta-1a), the world's leading treatment for relapsing forms of multiple sclerosis, and AMEVIVE® (alefacept), a complex bioengineered molecule for the treatment of certain kinds of chronic psoriasis. In 1993, Biogen entered into a license agreement ("Biogen License Agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. Since that time, Biogen has paid more than $35 million to Columbia under the Biogen License Agreement. Biogen has also entered into a variety of other agreements with Columbia, including research collaborations and license agreements.

10. Plaintiff Genzyme Corporation ("Genzyme") is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Genzyme was founded in 1981 and is also a pioneer in the biotechnology industry. Genzyme is dedicated to developing drugs and other products to treat patients with certain rare genetic disorders and other serious debilitating diseases. Genzyme has developed innovative treatments for lysosomal storage disorders, rare and progressive genetic conditions caused by missing enzymes. Genzyme has developed and commercialized CEREZYME® (imiglucerase), the only available enzyme replacement treatment for Type 1 Gaucher disease and THYROGEN® (thytotropin alpha) for use in thyroid cancer testing. Genzyme recently received FDA approval for FABRAZYME® (agalsidase beta) for the treatment of Fabry disease and ALDURAZYME® (laronidase) for treatment of MPS I (Mucopolysaccharidosis type-1). Genzyme is also the exclusive distributor of Biogen's AVONEX® in Japan.

11. Genzyme has entered into a variety of agreements with Columbia, including research collaborations. Columbia has also licensed certain screening technology (SAGE™, or serial analysis of gene expression) from Genzyme. In 1994, Genzyme entered into a license

agreement ("Genzyme License Agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. Genzyme has paid almost $25 million to Columbia under the Genzyme License Agreement.

12. Defendant Columbia is a New York non-profit corporation with a principal place of business in New York, New York. It is the owner by assignment of United States patents 4,399,216 ("'216 patent"), 4,634,665 ("'665 patent"), and 5,179,017 ("'017 patent"), which it licensed to Biogen and Genzyme under written license agreements (jointly, "License Agreements"). In addition to entering into the License Agreements with Biogen and Genzyme, under which it has accepted approximately $60 million dollars originating from Massachusetts, Columbia has also directed substantial and regular communications to plaintiffs in Massachusetts concerning the License Agreements and its patents. In 1993, Columbia brought suit to enforce the '216, '665, and '017 patents against a third party in this District. Columbia is also the owner of United States patent 6,455,275 ("'275 patent"), issued in 2002.

Jurisdiction and Venue

13. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201(a), and 2202. Also, because the amount in controversy exceeds $75,000, and the action is between citizens of different states, the Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

14. Biogen Idec herein seeks a declaratory judgment that the '275 patent is invalid and unenforceable because it has a reasonable apprehension that it will be sued by Columbia for infringement of the '275 patent. This reasonable apprehension is based at least in part upon (i) Biogen Idec's knowledge that as recently as September 1, 2004, Columbia asserted in the covenant not to sue filed in this Court that plaintiffs in the earlier action infringe the '275 patent and that the '275 patent is valid and enforceable; (ii) Columbia's repeated threats to various of its licensees that it would sue them for infringement of the '275 patent, including threats made in

court papers and court proceedings; (iii) the fact that Columbia has confirmed in writing that Biogen's affiliates are excluded from the scope of the covenant not to sue filed in court on September 1, 2004; (iv) the fact that Biogen Idec has never been a party to any license agreement with Columbia covering cotransformation technology; and (v) Biogen Idec's awareness of the facts set forth below.

15. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c).

Facts

A. Columbia's Original Cotransformation Patent Application

16. In the late 1970's, Richard Axel, Michael H. Wigler, and Saul J. Silverstein, scientists at Columbia University, carried out research on methods of inserting genes that code for certain proteins into the DNA of certain types of eukaryotic host cells. (Eukaryotic cells have a discrete nucleus, as distinguished from prokaryotic cells, which are principally bacteria and lack a structurally discrete nucleus.) Specifically, the Columbia scientists conducted experiments in cotransformation, a process of altering the genotype of a eukaryotic host or "recipient" cell by inserting into the cell both (a) a gene that codes for a desired protein and (b) a gene that codes for a "selectable marker." A selectable marker is a gene the expression of which confirms that the cell has been successfully transformed. For example, certain types of selectable markers may make a cell resistant to substances or conditions that would ordinarily kill the cell. A researcher can infer that this type of selectable marker has been incorporated into the cell's nuclear DNA if the cell survives in such hostile conditions. If the selectable marker has been incorporated into the host cell's nuclear DNA, it is likely that the cell has also incorporated the gene coding for the desired protein.

17. After conducting experiments concerning the cotransformation of certain types of mouse host cells with certain types of genes, Axel, Wigler, and Silverstein filed a patent

application in February 1980. This application, serial no. 06/124,513, ("'513 application") assigned to Columbia, issued (after amendment) as the '216 patent on August 16, 1983. The '216 patent had 73 claims, broadly covering (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, (c) processes for detecting cotransformed cells, and (d) cotransformed cells. It had a term of 17 years from the date of issuance, meaning that it would expire on August 16, 2000.

18. The research that led to the '216 patent was funded by the National Institutes of Health ("NIH"). NIH granted title to the invention to Columbia, but only upon certain conditions. Among these was the condition that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice."

B. Columbia's "Submarine" Patent Applications

19. Shortly before the '216 patent issued in 1983, Columbia filed a continuation application, serial no. 06/522,408 ("'408 application"). A continuation application is one that relies on the same disclosure, or specification, as an earlier, or "parent" application (in this case, the '513 application that matured into the '216 patent). Because a continuation relies on the same disclosure as its parent, it is an effort to obtain additional scope for the patent monopoly based on the same work disclosed in the original specification.

20. After almost three and one-half years of prosecution, the Patent Office allowed claims in the '408 application and issued the '665 patent in January, 1987. The claims of the '665 patent closely resembled the claims of the '216 patent. Specifically, the '665 patent claims (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, and (c) cotransformed cells. Because the subject matter of the '665 patent's claims was obvious in view of the '216 patent's broad claims, the Patent Office permitted the

'665 patent to issue only after Columbia filed a "terminal disclaimer," disclaiming the part of the patent's term that would have extended past the expiration date of the '216 patent. In this way, although Columbia received additional claims from the Patent Office, it did not obtain any additional time, or "term," in which it could legally exercise its monopoly over the subject matter claimed in the '216 (or '665) patent. Columbia made no attempt to deny that the claims of the '665 patent were obvious in view of the '216 patent.

21. Columbia's effort to obtain additional patents did not end with the '665 patent. In what was to become an oft-repeated tactic, Columbia filed another continuation application, serial no. 06/915,273 ("'273 application"), on October 3, 1986, again based on the specification of the '216 patent (and thus on the same research conducted in the late 1970's), shortly before the then-pending '408 application matured into the '665 patent. In the case of the '273 application, however, Columbia abandoned it after two years of prosecution and filed another continuation, serial no. 07/346,089 ("'089 application"), on May 2, 1989. Columbia then abandoned the '089 application after three years in favor of yet another continuation, serial no. 07/716,915 ("'915 application"), filed on June 18, 1991.

22. By repeatedly filing new applications based on the original specification and research, Columbia has continued, even up to the present, to prosecute claims based on the now decades-old research of Axel, Wigler, and Silverstein. Columbia's practice of "submarine" patenting allowed it to abuse the patent system by "surfacing" with a new patent many years or even decades after filing the original application. Keeping its original specification alive by filing one continuation or divisional application after another, Columbia sought to obtain new patents to capture the latest developments in the biotechnology industry.

23. In the case of the '915 application, which Columbia filed more than a decade after the original 1980 application, Columbia used its submarine patenting strategy to seek and obtain claims covering new advances the biotechnology industry had made during the intervening decade. For example, when Columbia filed the original '513 application in 1980, its researchers did not know that a type of Chinese hamster ovary ("CHO") cells would serve as the preferred host cell for producing desired proteins. Nonetheless, Columbia pursued claims to transformed CHO cells in the '915 application, filed June 18, 1991, and the Patent Office ultimately allowed those claims to issue as the '017 patent. Once again, however, the Patent Office allowed the claims only after Columbia filed a terminal disclaimer limiting the term of the '017 patent to the term of the original '216 patent. Columbia made no attempt to challenge the Patent Office's conclusion that the claims of the '017 patent were obvious in view of the claims already allowed in the '216 and '665 patents. In all, the '216, '665, and '017 patents contain more than 100 claims, all originating from Columbia's original patent application in 1980.

24. Columbia continued with its submarine patenting strategy. Shortly before the '017 patent issued in January 1993, it filed yet another continuation. Indeed, it ultimately filed **five** more continuations based on the original specification describing the early research of Axel and his colleagues. Instead of "surfacing" with a submarine patent, however, Columbia abandoned most of those continuations after desultory prosecution, only to file yet more continuation applications.

25. Effective June 8, 1995, Congress reformed the patent law to close many of the loopholes that had made submarine patenting possible. On June 7, 1995, the day before this change in the law went into effect, Columbia secretly filed **two** further continuation applications based on the original specification of the '513 application. Under the reform legislation, these

two applications were "grandfathered" because they were filed before the change in the law went into effect. In September 2002, one of these applications, serial no. 08/484,136 ("'136 application") issued after numerous amendments as the '275 patent now in suit. Because Columbia did not file a terminal disclaimer with respect to the '275 patent, the patent will not expire until 2019.

26. Yet another application filed the same day as the '136 application, serial no. 08/477,159 ("the '159 application"), is still pending at the Patent Office. In this application, Columbia is pursuing claims specifically directed at the commercial products of certain licensees, including products first marketed after the expiration of the '216, '665, and '017 patents.

C. Columbia's '636 Patent

27. At about the same time or shortly after he completed the research on which the original '513 application was based, Axel collaborated with another researcher, James Roberts, to carry out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins. Based on this research, which was closely related to the work that had led to the '216, '665, and '017 patents, Columbia filed a separate patent application on March 15, 1982. Columbia eventually abandoned this application, serial no. 358,206 ("'206 application"), in favor of filing a continuation. It repeated this tactic twice more, ultimately receiving U.S. patent 5,149,636 ("'636 patent") on September 22, 1992, more than a decade after it filed the initial '206 application. As discussed more fully below, Columbia never disclosed the '636 patent or its file history to the examiner in the '275 patent prosecution so that he could make a determination of its materiality to the patentability of the '275 patent.

D. Columbia's Licensing of the Axel Patents

28. Columbia granted a non-exclusive license under the '216, '665, '017, and '636 patents (and continuations thereof) to Biogen in 1993. Columbia entered into a similar non-exclusive license with Genzyme in 1994.

29. Each of the License Agreements provided for up-front royalty payments to Columbia even before plaintiffs brought any product to market. The agreements further provided for minimum annual payments regardless of sales of licensed products. Under the License Agreements, as detailed above, plaintiffs have paid approximately $60 million to Columbia. Columbia also licensed the patents to other biotechnology companies, reaping hundreds of millions of dollars in royalties.

30. Columbia's license agreements with plaintiffs and other biotechnology companies required the licensees to pay royalties not only on Columbia's issued patents such as the '216 patent, but also on patents issuing from "any and all divisions, continuations and continuations-in-part" thereof. This provision gave Columbia significant incentive to keep spawning "children" of the issued patents, including the '275 patent.

31. Section 2(b) of the License Agreements provides that "All rights granted by Columbia under this agreement are subject to any rights required to be granted to the Government of the United States of America, including without limitation any rights reserved or obligations imposed by the Government pursuant to 35 U.S.C. §200-211 [the Bayh-Dole Act], regulations thereunder and the determination letter to Columbia from the Department of Health and Human Services dated February 24, 1981, a copy of which is attached hereto...."

32. In the determination letter, the NIH granted title to the invention to Columbia, but only upon the condition that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade

practice." In addition, the regulations under which the NIH granted rights to Columbia empowered the NIH to assign the rights to an invention only "for the term of the patent or such lesser period as may be deemed necessary."

E. The Most Favored Licensee Provisions in the License Agreements.

33. Both the Genzyme License Agreement and the Biogen License Agreement include a provision, § 3(j) (hereinafter referred to as the "most favored licensee provision"), that reads as follows: "If Columbia, under substantially identical conditions, grants to a third party a license with respect to Licensed Products under Licensed Patent Rights, having royalty rates more favorable to such third party than those set forth herein, Columbia will give Licensee the benefit of such rates." Under this provision, in addition to giving Biogen and Genzyme the benefit of more favorable rates, Columbia also has an implicit obligation to disclose to Biogen and Genzyme any license agreements with third parties that have more favorable royalty rates for the third party than those set forth in the Biogen and Genzyme License Agreements.

34. Both the Genzyme License Agreement and the Biogen License Agreement also include a provision, § 3(i) (hereinafter referred to as the "stacking royalties provision"), that reads in pertinent part as follows: "If the manufacture, use or sale by Licensee of a Licensed Product in any country ... would infringe a patent in that country, which patent is owned by a third party, Licensee shall be entitled to deduct from the royalties due from Licensee to Columbia ... certain royalties paid by Licensee to such third party for a license under such patent. Specifically, Licensee may deduct from the royalties due from Licensee to Columbia based upon sales of such Licensed Products in such country up to one third of the royalties paid by Licensee to such third party based upon such sales, provided such deductions shall not exceed one-third of the amount of royalties due from Licensee to Columbia on such sales."

35. These stacking royalties provisions allowed Genzyme and Biogen to deduct from their royalty payments to Columbia under the '216, '665, and '017 patents only **one third** of any royalty payments that Genzyme or Biogen made to third parties for the same products, provided the total deduction did not exceed one third of the amount owed to Columbia.

36. Upon information and belief, the licenses of one or more other licensees of Columbia's cotransformation patents include royalty rates that under substantially similar conditions are more favorable to the licensee than those set forth in the Biogen and Genzyme licenses. In particular, upon information and belief, other licenses have a stacking royalties provision that does not limit deductions to one third of royalty payments made by the licensee to third parties. A licensee having such a stacking royalties provision in its license would be entitled to deduct **the full value** of any royalty payments made to third parties for the same product, provided the total deduction did not exceed one third of the amount owed to Columbia, and would, thus, enjoy the benefit of a more favorable royalty rate payable to Columbia than Genzyme and Biogen.

37. Columbia never notified either Genzyme or Biogen that the licenses of one or more other licensees included more favorable royalty rates than the royalty rates granted to Genzyme and Biogen. .

F. Columbia's Failed Attempt to Persuade Congress to Extend Its Patent Monopoly

38. The '216, '665, and '017 patents expired in August, 2000. Shortly before they were due to expire, Columbia embarked on an aggressive lobbying campaign to obtain special legislation from Congress extending the term of the '216 patent. Columbia claimed, among other things, that the income stream from the patent was "absolutely critical" and the "single most important source of free and clear funding" for the university. Notwithstanding the

importance of the royalty stream to Columbia, the university claimed that the biotechnology industry was not burdened by paying these royalties, which Columbia characterized as "nominal."

39. During its campaign to persuade Congress to extend the term of the '216 patent, Columbia described its patent as pioneering, and as having great breadth and scope. Columbia represented to Congress that its '216 patent "covers the process for transforming animal cells so they can produce proteins used in biological pharmaceutical products." According to Columbia, it was the '216 patent that "makes it possible to generate the cell lines that are needed to produce patented drugs," specifically identifying Biogen's AVONEX® for treatment of multiple sclerosis and Genzyme's CEREZYME® for treatment of Gaucher's disease as two such drugs. As Columbia told Congress, its patent broadly claimed both "the cotransformed cells and the process of making them."

40. In its submissions to Congress, Columbia requested urgent action on its patent term extension request, representing that "Columbia's cotransformation patent expires on August 16, 2000." Columbia did not tell Congress that Columbia was simultaneously prosecuting secret patent applications that sought the issuance of new patents, with new 17-year terms, claiming the same cotransformation technology. And, just as Columbia did not tell Congress that it was seeking further patent term by pursuing additional continuation applications, Columbia did not tell the Patent Office what it told Congress, namely, that it believed the '216 patent to have extremely broad claim scope, covering both cotransformed cells and the process of making them.

41. Columbia's request for extension of the term of the '216 patent met with widespread public outcry, and Congress rejected it, recognizing that Columbia had already reaped rich rewards from its seventeen-year patent monopoly. Congress decided that

biotechnology companies should not be burdened by paying additional royalties for the period after the expiration of the '216 patent under their licenses with Columbia. Thus, the inventions claimed in the '216, '665, and '017 patents passed into the public domain in August 2000. This meant that plaintiffs, and other biotechnology companies, were free to develop and sell recombinant biological products without the economic burden of paying further royalties to Columbia. Referring to Congress's rejection of Columbia's proposed special legislation, Columbia's spokesperson said, "I do not believe there's a next step in this patent extension story ... it's an issue that's by us. ... Either you get the patent extended or it expires, and there's just no way to go back after it expires, so we're not going to be making any attempt."

G. The Surfacing of the '275 Submarine Patent

42. In fact, however, Columbia had an alternative plan already in place to extend the patent monopoly on its cotransformation technology. As previously set forth, Columbia had in 1995, unbeknownst to its licensees, Congress, or the public, filed two additional patent applications relying on the same patent disclosure and specification that its researchers had made some fifteen years earlier and that had been the basis for the '216, '665, and '017 patents.

43. Since these continuation applications were the last Columbia could file under the pre-reform patent prosecution rules, Columbia could not simply abandon them and further drag out the patent prosecution process as it had done so many times before. If it had filed new continuation applications after June 7, 1995, any patent to issue from those applications would have expired, under the new rules, in February 2000. Instead, Columbia employed dilatory tactics to keep its June 7, 1995 continuation applications pending, including filing for extensions and filing notices of appeal to gain additional time. These tactics delayed the issuance of additional patents and thereby extended the term of those patents as far as possible into the future.

44. Using these tactics, Columbia strung out the prosecution of the continuation applications to such an extent that one application is still pending eight years after filing and the other did not mature into a patent until more than seven years after its filing date. That patent, the '275 patent, issued on September 24, 2002, almost twenty-three years after the filing of the original specification and more than two years after the expiration of its three earlier cotransformation patents. It was the product of **eight** continuing or divisional applications, of which five were abandoned. During prosecution of the '275 patent, which did not even **begin** until fifteen years after Columbia filed the original application, Columbia sought extensions of time amounting to some twenty-two months, filed two notices of appeal that it did not pursue, and added many new claims at a late stage in the prosecution.

45. Columbia's dilatory prosecution of the '275 patent and its predecessor applications was not Columbia's only abuse of the patent process. Columbia also resorted to misleading the patent examiner to obtain the patent, as set forth below.

46. Like the '017 patent, the '275 patent purports to claim developments in biotechnology that the Columbia researchers either had not achieved or had been unaware of at the time they filed the '513 application in 1980. Like the '017 patent, the '275 patent claims transformed CHO cells, a cell type that the inventors had never, as of the filing date, used successfully as a vehicle for the production of medically valuable proteins. It also claims methods of producing and recovering protein materials that the inventors had not successfully practiced as of the time they filed the original '513 application. It also claims a "DNA construct," a term that does not appear in the original specification and came into use in the biotechnology industry only later.

47. Unlike the '017 patent, however, the '275 patent issued **without any terminal disclaimer**. Thus, although the discoveries on which it is based had to have been made before the original February 1980 filing date, the '275 patent, were it valid, would remain in effect until **September 2019**. In effect, the combined terms of the new patent and the '216 patent run for thirty-six years, from 1983 to 2019 (with a two-year gap between the expiry of the '216 patent and the issuance of the '275 patent). This combined term is far in excess of the limited monopoly contemplated by the Patent Act and the NIH determination letter, and would significantly burden the efforts of plaintiffs and other biotechnology companies to develop new innovative recombinant therapeutic and diagnostic products.

48. Had Columbia filed the terminal disclaimer that should properly have accompanied the '275 patent, that patent would have expired along with the three earlier patents on August 2000 – before it issued.

H. Columbia's Demands Under the License Agreements

49. Shortly after the '275 patent issued, Columbia announced to Biogen, Genzyme, and other licensees that, contrary to their expectations that royalty payments under the License Agreements had come to an end, the issuance of the '275 patent had triggered the obligation to pay royalties under their License Agreements once again. For example, by letter to Biogen dated October 3, 2002, Columbia advised Biogen of the issuance of the '275 patent and noted that "Columbia does not agree" that Biogen's last payment was "its last royalty owed." Thus, although plaintiffs believed that their royalty obligations to Columbia had expired with the expiration of the '216, '665, and '017 patents, Columbia demanded royalty payments for another seventeen years, the term of the '275 patent.

I. Litigation Relating To The '275 Patent

50. On July 15, 2003, Biogen, Genzyme and Abbott Bioresearch Center, Inc., filed suit against Columbia in the District of Massachusetts alleging the invalidity and unenforceability of the '275 patent. Genentech, Inc., another licensee, had sued Columbia in the Northern District of California in April 2003 to challenge the '275 patent. Thereafter, several additional cases were filed alleging that the '275 patent was invalid and enforceable. On October 31, 2003, Columbia sued its licensees Johnson & Johnson and Ares Trading S.A. for a declaration that the '275 patent is valid and enforceable, and for breach of contract, alleging that these companies owed royalties on the '275 patent.

51. When the companies that filed suit against Columbia attempted to move their cases forward, Columbia stalled. Columbia refused to permit discovery and sought to stay various cases while it filed motions under 28 U.S.C. § 1404 to transfer venue of each of the cases to the Northern District of California. In its motion papers, Columbia contended that the alternative of multidistrict consolidation would be inappropriate. Later, with several such motions briefed and pending, Columbia reversed course, abandoned its venue motions, and moved for multidistrict transfer of all pending cases to the Northern District of California under 28 U.S.C. § 1407.

52. On April 8, 2004, the Judicial Panel on Multidistrict Litigation ("JPML") issued a Transfer Order, granting Columbia's request to consolidate the several cases for pretrial proceedings but denying its request to transfer the actions (the "MDL cases") to the Northern District of California. Instead, the JPML ordered transfer of the MDL cases to the District of Massachusetts, assigning them to the Honorable Mark L. Wolf (the "MDL court"). Since that date, the litigation has proceeded in the District of Massachusetts. The original plaintiffs in the Multidistrict Litigation were Biogen Idec MA, Inc. (formerly Biogen Inc.); Genzyme

Corporation; Abbott Bioresearch Center, Inc.; Baxter Healthcare Corporation: Serono, Inc.: Ares Trading, S.A.; Wyeth; Genetics Institute, Inc.; Amgen, Inc.: Genentech, Inc.; Immunex Corporation; and Johnson & Johnson ("MDL plaintiffs").

J. Reexamination and Reissue Proceedings

53. On February 25, 2004, a third party, the Public Patent Foundation, filed a Request for Ex Parte Reexamination of the '275 patent on the grounds of double patenting. Columbia took no action upon learning of the reexamination request. It did not file its own reexamination request, it did not file a reissue application, and it did not retract its demands to the MDL plaintiffs for payment of royalties under the '275 patent.

54. The Patent Office granted Public Patent Foundation's Request for Reexamination on May 6, 2004. Columbia took no action at the time in response to this development. Instead, on May 27, 2004, this Court issued an Order that, among other things, directed the parties to address the implications of the Patent Office's decision to reexamine the '275 patent.

55. On June 10, 2004, over a month after the Patent Office's grant of reexamination, Columbia moved for a stay of the MDL proceedings. Columbia based this motion on the reexamination proceeding and its intent to file a reissue application with the Patent Office. Columbia filed its reissue application on June 18, 2004. Its application seeks to broaden the scope of the claims in the '275 patent.

56. Columbia could have filed a reexamination request or a reissue application under 35 U.S.C. § 251 at any time after the '275 patent issued in September 2002, but did not do so until June 2004, almost four months after the filing of the request for reexamination and a mere three months before the expiration of the two-year window for seeking a broadening reissue.

57. In its reissue application, Columbia seeks to expand the scope of the '275 patent by adding no fewer than seventeen new, broader claims and by amending its existing claims to

enlarge their breadth as well. In other words, after waiting to file the reissue application until **nearly two years after issuance** of the '275 patent and **more than twenty-four years** after filing the original patent application, Columbia is using the reissue application on the '275 patent to begin prosecuting new, broader claims. Moreover, now that Columbia has filed for a broadening reissue, it can seek additional broadening claims even after the two-year deadline for broadening reissue applications, and it can appeal from any new claims rejected by the examiner, dragging out the prosecution still further. Columbia tries to justify the reopening of prosecution, some twenty-four years after filing its original application and after having obtained dozens of claims in three earlier issued patents, on the ground that it "failed to obtain the full scope of protection" for its 1980 invention.

58. Columbia's reissue application is the next chapter in its attempt to string out its patent prosecution. In the ex parte Patent Office reissue and reexamination proceedings, Columbia has substantial control over the length of the process. Columbia has already begun to exploit the numerous opportunities for delay provided by the rules for reexamination and reissue.

59. For example, at a June 22, 2004 hearing, in seeking to persuade the Court that reissue and reexamination would provide an efficient resolution of plaintiffs' claims, Columbia told the Court that "it's very common to ask for reissue, and that's why there's a procedure to merge the two proceedings when someone asks for a reexamination. But it both happened together on the same track by the same examiner so nothing gets slowed down. That's what we want to happen. We want to get this done quickly in the Patent Office too." Tr. at 90-91.

60. On July 7, 2004, however, just over two weeks later, and without informing the Court, Columbia filed a request to stay the reexamination of the '275 patent until completion of the reissue proceedings which it did not initiate until almost two years after the '275 patent

issued. In its request to stay the reexamination, Columbia stated that "a merger of the two proceedings is not the preferred approach because in the above-identified reexamination, Patentees will not be permitted to obtain the broadened claims which Patentees are seeking, and are permitted to obtain, in their reissue application." Columbia also maintained that merger would be inappropriate because the obviousness-type double patenting issues that the Public Patent Foundation proposed for consideration on reexamination will be resolved in the reissue proceedings that Columbia initiated. If Columbia's request to stay the reexamination is allowed, the reexamination will not even begin until after the conclusion of the reissue proceedings.

61. In other words, Columbia not only plans to take the maximum time to replay and fine-tune its previous seven-year prosecution of the '275 patent, it proposes that when the reissue concludes, the patent will then, and only then, enter the reexamination proceeding instituted by the Public Patent Foundation.

K. License Termination and Motion for Preliminary Injunction

62. On March 9, 2004, after the request for reexamination was filed, Columbia again asserted the '275 patent against Biogen and Genzyme and others. In particular, Columbia sent letters to Biogen and Genzyme asserting that they were in breach of their License Agreements and stating its intention to terminate the licenses for non-payment of royalties under the '275 patent.

63. On April 7, 2004, Biogen and Genzyme moved for a preliminary injunction to enjoin the termination of their licenses. In their motion papers, they demonstrated a high likelihood of success on the merits, showing that the '275 patent is invalid for double-patenting and unenforceable by reason of prosecution laches. In opposing the motion, Columbia said not one word in defense of its patent, yet it still maintained that it had properly terminated the licenses of Biogen and Genzyme for failure to pay royalties on the '275 patent.

64. In demonstrating their uncontested likelihood of success on the merits, Biogen and Genzyme submitted sixty-five pages of briefing, as well as nearly four hundred and fifty pages of supplemental materials, including a fifteen-page substantive declaration of Harvey F. Lodish, Ph.D. The Court addressed the motion during a full-day hearing on June 22, 2004. On August 13, 2004, the Court issued a thirty-two page written order denying the motion while finding plaintiffs had made a "strong showing" of likelihood of success on the merits.

L. The Covenant Not To Sue and License Reinstatement

65. On September 1, 2004, Columbia filed a limited "covenant not to sue" on the '275 patent. The covenant retained the right to sue for any products and processes introduced by the MDL plaintiffs after September 1, 2004, and the right to sue on any patents subsequently issued from pending patent applications. Columbia asserted that this limited covenant eliminated any case or controversy with respect to nearly all claims against it and demanded that each of the MDL plaintiffs withdraw their complaints **by the following afternoon**. When the MDL plaintiffs did not capitulate to this sudden demand, Columbia filed an "emergency" motion to dismiss on September 2, 2004.

66. At an October 6, 2004 hearing before the Court on the "emergency" motion to dismiss, in response to the MDL plaintiffs' showing that they had a reasonable apprehension of suit for infringement, Columbia agreed to expand the scope of the covenant not to sue for infringement of the pre-reissue '275 patent claims to include **all** products made or sold by the MDL plaintiffs at any time, whether before or after the date of the covenant. Nevertheless, despite direct requests that they do so, Columbia refused to include the MDL plaintiffs' affiliates -- such as Biogen Idec -- within the protection of the covenant.

67. Although Columbia had terminated Biogen's and Genzyme's License Agreements nearly six months earlier and obtained the Court's ruling confirming that the licenses were

terminated, in a letter to the Court on September 3, 2004, Columbia stated that its notices of termination, on the basis of which it had opposed the preliminary injunction motion, were "ineffective." Subsequently, by letter of September 13, 2004, Columbia wrote to Genzyme and Biogen "withdraw[ing] the notices of termination," but expressly preserving all grounds for termination other than failure to pay royalties on the '275 patent.

M. Settlements Extracted By Columbia In Reliance Upon The '275 Patent.

68. After Columbia sent its termination notices in March 2004, it sought to exploit the '275 patent, and the costs and uncertainty of litigation, by attempting to extract settlements from several plaintiffs, including Genzyme, before Columbia withdrew its termination notices. On information and belief, Columbia obtained financial settlements from Ares Trading, Serono, and Baxter in May and June of 2004 with respect to the '275 patent, notwithstanding their allegations of the invalidity and unenforceability of that patent.

69. Columbia sought to obtain a financial settlement from Genzyme in April 2004. As a condition of conducting settlement negotiations, Columbia required Genzyme to sign a confidentiality agreement prohibiting any communications between Genzyme and its outside litigation counsel Foley Hoag LLP concerning the terms of Columbia's settlement proposal.

70. Columbia admits that that it uses the existence of its pending patent applications seeking to extend its patent monopoly to increase its leverage over potential licensees. Indeed, Columbia tried to obtain the assistance of this Court in this regard, maintaining that the "disclosure of Columbia's pending patent application will unfairly disadvantage Columbia in charting its litigation and settlement strategy with each of the multiple plaintiffs in this action," and expounding that it wanted to "ensure that the individuals advising the plaintiffs in this litigation, and in any settlement discussions, do not have access to this information at all...."

71. Columbia's actions represent an abuse of the patent system and the legal process. It has continued for more than twenty-four years to prosecute a 1980 patent application, going so far as to file a broadening reissue application in 2004. That Columbia delayed filing the reissue application while dragging plaintiffs through months of costly procedural motions makes clear that it also seeks judicial delay, and to ensure that plaintiffs face a moving target. It has engaged in an ongoing strategy to delay court proceedings that plaintiffs brought to remedy Columbia's abusive conduct in the Patent Office, including forcing Biogen and Genzyme to incur substantial costs in defending their licenses, only to assert after the fact that its termination notices were "ineffective." Recognizing that the '275 patent is invalid and unenforceable, Columbia has nevertheless used the patent to its advantage against its licensees while pursuing tactical maneuvers designed to delay or prevent any judicial challenge to the patent.

72. Plaintiffs Biogen and Genzyme have suffered substantial harm, including unnecessary and vexatious costs of litigation and damage to their reputations as a result of Columbia's attempts to enforce the invalid and unenforceable '275 patent, its serial and conflicting motions to transfer earlier lawsuits, its breach of the most favored licensee provisions of their licenses, its wrongful termination of their License Agreements, its opposition to their motion to enjoin the termination, its motion to stay the prior litigation, its threats of infringement suits, and its bad faith conduct of the earlier litigation.

Claims

Count I: Abuse of Process

73. Plaintiffs incorporate all prior paragraphs of this complaint.

74. The '275 patent is invalid and unenforceable.

75. Through its conduct in the litigation over the validity and enforceability of '275 patent, Columbia has manipulated and abused the judicial process for ulterior and illegitimate

purposes, including, among other purposes, to prolong its patent monopoly beyond the statutory term, to extract favorable settlements securing royalty payments on an invalid and unenforceable patent, and to prevent, delay, and/or obtain unfair advantage in connection with a judicial determination of the validity and enforceability of its patent.

76. Because of Columbia's abuses of the judicial process, Biogen and Genzyme have suffered damages.

Count II: Breach of Contract and of the Implied Covenant of Good Faith and Fair Dealing

77. Plaintiffs incorporate all prior paragraphs of this complaint.

78. The Biogen and Genzyme License Agreements contain an implied covenant of good faith and fair dealing. That covenant, along other things, prohibits conduct that would destroy or injure plaintiffs' rights to enjoy the benefit of those agreements.

79. Columbia has breached the implied covenant of good faith and fair dealing. Columbia's deliberate breach of the implied covenant of good faith and fair dealing has impaired Biogen's and Genzyme's rights to enjoy the benefit of the License Agreements, thereby causing damage and injury to Biogen and Genzyme.

A. Wrongful Termination

80. The '275 patent is invalid and unenforceable.

81. In March 2004, Columbia wrongfully sent termination letters to Biogen and Genzyme, and their licenses were terminated, based upon Columbia's assertion of an invalid and unenforceable patent, the '275 patent. As a result of Columbia's wrongful termination, Biogen and Genzyme suffered damages.

B. Breach of Section 2(b)

82. Columbia is in breach of Section 2(b) of the License Agreements because Columbia's actions and conduct, including its efforts to enforce and extend the life of an invalid

and unenforceable patent, its demands for royalties and fees under the License Agreements, its attempts to prolong its patent monopoly beyond the statutory term and its efforts to prevent a judicial determination of the validity and enforceability of its patent, violate Columbia's obligations to the refrain from engaging in repressive licensing practices, and have caused and continue to cause Biogen and Genzyme to suffer damages.

C. Breach of Section 3(j)

83. Columbia is also in breach of section 3(j) of the License Agreements, the most favored licensee provision, because it neither disclosed to Biogen or Genzyme, nor gave Biogen and Genzyme the benefit of, license agreements with third parties that provided more favorable royalty rates to the licensees than those provided to Biogen and Genzyme.

84. As a direct and proximate result of Columbia's failures to perform, Genzyme has been damaged by paying excessive royalties. Genzyme is entitled to repayment of any royalties paid in excess of the lesser amounts it would have paid had Columbia not violated the most favored licensee provisions of its license. Further, Biogen and Genzyme have been kept in ignorance of their rights under their License Agreements and have been deprived of their rights to enjoy the benefit of their License Agreements, thereby causing damage and injury. Biogen and Genzyme are also entitled to examine licenses held by other parties in order to enforce their most favored licensee provisions.

Count III: Violation of MASS. GEN. LAWS ch. 93A, § 11

85. Plaintiffs incorporate all prior paragraphs of this complaint.

86. Plaintiffs and Columbia are engaged in the conduct of trade or commerce within the meaning of Mass. Gen. Laws c. 93A §§ 1 and 11.

87. Columbia's acts, as described above, constitute unfair and deceptive acts and practices in the conduct of trade or commerce, in violation of Mass. Gen. Laws c. 93A §§ 2 and 11.

88. The '275 patent is invalid and unenforceable.

89. Columbia's unfair deceptive acts in connection with the '275 patent and the related litigation wrongfully impaired plaintiffs' rights under the License Agreements and plaintiffs' access to intellectual property that should have entered the public domain. Columbia has also engaged in unfair and deceptive acts and practices by using an invalid and unenforceable patent to wrongfully leverage its bargaining position and attempt to extract illegitimate financial gain.

90. Columbia's unfair and deceptive acts and practices occurred primarily and substantially within Massachusetts.

91. Columbia's unfair and deceptive acts and practices constitute knowing and/or willful violations of Mass. Gen. Laws c. 93A §§ 2 and 11.

92. As a consequence of Columbia's unfair and deceptive acts and practices, plaintiffs have incurred damages.

93. As a direct and proximate result of the foregoing knowing and willful deceptive acts and practices of Columbia, plaintiffs are entitled to multiple damages in an amount to be determined, as well as reasonable attorneys' fees.

Count IV: Declaration of Invalidity of the '275 Patent

94. Plaintiffs incorporate all prior paragraphs of this complaint.

95. Biogen Idec is entitled to and seeks a declaratory judgment that the '275 patent is invalid for, without limitation, non-statutory obviousness-type double-patenting, because each of

the claims of the '275 patent is the same as, or merely an obvious variant of, inventions claimed in other patents owned by Columbia, singly or in combination.

96. Biogen Idec is further entitled to and seeks a declaratory judgment that the '275 patent is invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

97. There is an actual controversy between Biogen Idec and Columbia concerning the validity of the '275 patent.

Count V: Declaration of Unenforceability of the '275 Patent for Prosecution Laches

98. Plaintiffs incorporate all prior paragraphs of this complaint.

99. Biogen Idec is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable by reason of prosecution laches, specifically, Columbia's unreasonable delay in prosecuting the applications that resulted in the '275 patent and its continuing activities in connection with the reexamination and reissue proceedings.

100. There is an actual controversy between Biogen Idec and Columbia concerning the enforceability of the '275 patent.

Count VI: Declaration of Unenforceability of the '275 Patent for Inequitable Conduct

101. Plaintiffs incorporate all prior paragraphs of this complaint.

102. Biogen Idec is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable by reason of inequitable conduct, specifically, as set forth below, Columbia's (a) advancing misleading statements to the examiner about whether its claims were patentable, (b) failure to make timely disclosure of a related application and its prosecution history, (c) failure to disclose the '636 patent and its prosecution history, and (d) failure to disclose statements it had made to Congress that were inconsistent with positions it took during prosecution of the '275 patent.

103. There is an actual controversy between Biogen Idec and Columbia concerning the unenforceability of the '275 patent for inequitable conduct.

1. Misleading Statements Regarding the Patentability of Claims of the '275 Patent

104. As previously set forth, Columbia held three patents that all relied upon the same original disclosure and that expired in August, 2000: the '216, '665, and '017 patents. To overcome double-patenting rejections, Columbia filed terminal disclaimers that ended the term of the '665 patent and the '017 patent on the expiration date of the '216 patent.

105. During prosecution of the '275 patent, in an office action dated February 3, 1998, the examiner rejected all pending claims for double patenting over the issued claims of the '017 patent. These rejected claims, then numbered 126-132, were drawn to DNA constructs for transforming cells and, in the case of claim 132, eukaryotic cells transformed using such constructs.

106. In response to the February 3, 1998 office action, on July 24, 1998, Columbia canceled claim 132, the only claim to transformed eukaryotic cells then pending. Columbia also argued that the remaining DNA construct claims were not subject to double-patenting rejection over the '017 patent. Columbia stated: "The 'right to exclude' provided by claims 1-4 of U.S. 5,179,017 relates to transformed Chinese Hamster Ovary (CHO) cells. Thus, the 'right to exclude' provided by U.S. 5,179,017 relates only to the manufacture, use and sale of CHO cells. In contrast, the 'right to exclude' which would be provided by claims 126-131 of the subject application would, if allowed, relate to the manufacture, use and sale of DNA constructs." July 24, 1998 Response, pp. 2-3 (emphasis in original). Thus, Columbia acknowledged that the claims that issued in the '017 patent relate to transformed CHO cells.

107. During prosecution of the '275 patent, in an amendment filed June 14, 2001, Columbia added numerous new claims, some of which ultimately issued in the '275 patent. The Remarks accompanying this amendment stated that the new claims were "not subject to the obviousness-type double-patenting rejection." It then listed the claims in groups and explained why each group was not subject to rejection on double-patenting grounds. In each case, however, Columbia presented argument only about why the claims were not subject to double-patenting in view of the '216 patent, not the '017. Because the claims about which Columbia presented these arguments were newly submitted, Columbia did not make its assertions about double-patenting in response to an examiner's rejection of claims; rather, Columbia made these statements preemptively, to deter the examiner from issuing double-patenting rejections. By this time, a new examiner, who had not been involved in the double-patenting rejections in February 1998, was now assigned to the case.

108. In asserting that the new claims in the '136 application (which led to the '275 patent) were not subject to double-patenting rejections over the '216 patent, Columbia misled the Patent Office by failing to draw the new examiner's attention to the claims of Columbia's other patents, and most significantly the '017 patent. The claims of the '017 patent, which provided the basis for double patenting rejections in 1998 by the examiner at that time, are substantially similar to the new claims Columbia added to the '136 application in June 2001 and could have provided a basis for a double-patenting rejection of the new claims.

109. Columbia's statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double patenting rejection could be made. Moreover, in view of Columbia's statements in the

July 24, 1998 Response conceding that the '017 patent relates to transformed CHO cells, Columbia was aware that the newly asserted claims, many of which were directed to transformed CHO cells, were vulnerable to double-patenting rejections over the '017 patent claims. Given the facts recited above, it is reasonable to infer that Columbia's misleading omission of Columbia's other issued patents, particularly the '017 patent, from its preemptive argument to the new examiner was a deliberate and intentional effort to draw attention away from the other grounds on which the claims could be rejected for double-patenting and thus to mislead the examiner.

110. Moreover, the very arguments that Columbia raised to head off double patenting rejections of the newly added claims were themselves substantially false and misleading. For example, Columbia stated that certain of the new claims were not vulnerable to double patenting rejections because "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." In fact, issued claim 54 of the '216 patent recites transforming a eukaryotic cell "with a molecule which is **formed by linking** one of said foreign DNA I molecules to a DNA II molecule."

111. As another example, Columbia stated that other of the newly added claims were not vulnerable to double patenting rejections because "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, issued claim 54 of the '216 patent (for example) recites transforming cells with a molecule formed by **linking** a DNA I to an **amplifiable** DNA II, and culturing the transformed cells under conditions "permitting survival or identification of eukaryotic cells which have acquired multiple copies of said amplifiable gene." Because DNA II is an amplifiable gene linked to DNA I, it is inherent in the claim that the end result is both amplified DNA I and amplified DNA II. Therefore, contrary

to Columbia's assertion, claim 54 does indeed make obvious a recitation that both DNA I and DNA II are amplified.

112. In an office action on the '136 application dated July 30, 2001, the examiner rejected a number of the newly added claims for, among other things, obviousness-type double-patenting over claim 73 of the '216 patent.

113. In response to this office action, in a paper filed January 30, 2002, Columbia again stated that the claims were not obvious in view of the '216 patent for the same reasons it had asserted in its June 14, 2001 amendment. Like the June 14, 2001 amendment, the January 30, 2002 paper made no mention of the '017 patent or the fact that the claims of the '017 patent were substantially similar to the claims Columbia was then seeking.

114. Like the June 14, 2001 Remarks, Columbia's January 30, 2002 statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double-patenting rejection could be made. Upon information and belief, Columbia presented these statements with intent to mislead the patent examiner. The '275 patent is therefore unenforceable due to inequitable conduct in its prosecution.

2. Failure to Disclose Rejection of Substantially Similar Claims in '159 Application

115. As set forth above, on June 7, 1995, Columbia filed two continuation applications relying on the original disclosure filed in February 1980. One of these applications matured into the '275 patent. The other, serial no. 08/477,159 ("the '159 application"), is still pending today.

116. The '159 application included claims directed to subject matter that is substantially similar to the subject matter claimed in the '275 patent. For example, claim 135 of the '159 application was substantially similar to issued claim 14 of the '275.

117. On April 22, 1997, the examiner then assigned to the '159 application issued an office action rejecting claims in the '159 application for double patenting over the '017, '216, and '665 patents, including claim 135. The claims were also rejected for failure to satisfy 35 U.S.C. § 112. Because these claims are substantially similar to claims that issued in the '275 patent, these rejections are highly material to the patentability of those claims.

118. Despite the materiality of the '159 application and the rejections of claims substantially similar to the '275 claims in April 1997, Columbia did not make the existence of the '159 application of record in the '275 prosecution until May 6, 2002, nearly **seven years** into the co-pendency of the two applications and a mere three months before allowance of the claims of the '275 patent. Even then, Columbia failed to disclose to the examiner the prior double-patenting rejections, by a different examiner in the '159 prosecution, of claims substantially similar to those in the '275 application. This contrary decision by another examiner was material to the patentability of the '275 claims.

119. Given the facts recited above, it is reasonable to infer that Columbia's unreasonable delay in disclosing the '159 application, as well as its failure to disclose the rejection of substantially similar claims by a different examiner in that case, was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

3. Failure to Disclose '636 Patent and Rejection of Substantially Similar Claims

120. As previously set forth, Columbia's '636 patent, which issued in 1992, was pending during the prosecution of several of the submarine applications that ultimately led to the '275 patent. The claims of the '636 patent include claims directed to (a) processes for generating multiple copies of a foreign DNA I in eukaryotic cells and (b) product claims directed to eukaryotic and mammalian cells into which foreign DNA I has been introduced by the claimed processes. These product-by-process claims of the '636 patent overlap in scope with at least claim 5 of the '275 patent and its dependent claims. The '636 patent was prosecuted by the same law firm that prosecuted the '216 patent and its continuations and divisional applications (along with foreign counterparts, "'216 patent family"), including the '275 patent.

121. Columbia never disclosed the '636 patent to the examiner or made it of record during the prosecution of the '216 patent family, despite the fact that the '636 patent could have provided a basis for a double patenting rejection of various claims in the numerous applications that led to the '275 patent. Thus, the existence of the '636 patent was material to the patentability of claims Columbia prosecuted in the '216 patent family, including at least one claim that issued as part of the '275 patent.

122. The '636 file history includes rejections of claims that are substantially similar to claims pursued during prosecution of the '216 patent family, including the '275 patent. For example, in application 06/683,251, the second application in the chain that led to the '636 patent, Columbia pursued two claims, 24 and 25, that are substantially similar to issued claim 5 of the '275 patent. In an office action dated June 3, 1986, the examiner rejected these claims as anticipated by or obvious in view of the '216 patent or a related published international application. Undaunted, Columbia pursued these same claims in application 07/103,807, the

third application in the chain leading to the '636 patent. They were again rejected, on the same grounds, in an office action dated March 24, 1988. These rejections evidence the closeness between the '216 patent family (which includes the '275 patent) and the claims Columbia was seeking in prosecuting the '636 patent. Thus, it is highly likely that a patent examiner evaluating the claims proposed in the applications leading up to the '275 patent would have wanted to be informed of the rejection, by a different examiner, of claims pursued in prosecution of the applications leading up to the '636 patent. Those rejections are therefore material to the patentability of the claims asserted during the prosecution of the '216 patent family, including the claims that ultimately issued in the '275 patent.

123. Notwithstanding the more than **twenty years** between the filing of the application that led to the '636 patent and the issuance of the '275 patent, and the many information disclosure statements Columbia filed in the prosecution of the '216 patent family during that time period, Columbia failed to make the pendency, the issuance, or any part of the file history of the '636 patent of record in any of the applications that led to the issuance of the '275 patent.

124. As the owner of the '636 patent as well as the '275 patent, Columbia was aware of the materiality of the '636 patent and its file history to the '275 patent, as was its patent counsel, who prosecuted both the '636 and the '275 patents. Given the singular commercial and financial importance of the '216 patent family, it is reasonable to infer that Columbia's strategy for prosecuting that patent family and, in particular, the applications leading up to the '275 patent, did not arise from inattentiveness or accident. Given the facts recited above, it is also reasonable to infer that Columbia's failure to disclose the '636 patent or its file history during the prosecution of the '216 patent family was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

4. Failure to Disclose Statements to Congress Inconsistent With Positions Taken Before the Patent Office

125. As previously set forth, as the expiration date of the '216, '665, and '017 patents loomed, Columbia undertook a lobbying campaign in an attempt to secure from Congress an extension on its monopoly over the technology claimed in the '216 patent. In the course of that campaign, Columbia made numerous statements to Congress that were inconsistent with positions it took in its concurrent prosecution of the '275 patent claims in the Patent Office. In its statements to Congress, Columbia emphasized the breadth and pioneering scope of the '216 patent. Indeed, Columbia told Congress that its patent broadly claimed both "cotransformed cells and the process of making them." In its statements to the Patent Office, on the other hand, Columbia argued that the scope of the '216 patent was much more limited. Columbia never disclosed to the Patent Office during prosecution of the '275 patent the inconsistent representations it made to Congress in 2000, in violation of its duty of candor to the Patent Office under 37 C.F.R. § 1.56.

126. Columbia also made inconsistent representations to Congress and the Patent Office on narrower issues. For example, Columbia told Congress that the '216 patent covered both what is known as "linked" cotransformation as well as what is known as "unlinked" cotransformation. With respect to linked cotransformation, Columbia told Congress that under the '216 patent, "[t]he genes of interest can be joined together in a single DNA construct prior to their introduction into the cell of interest." Columbia also asserted to Congress that "[t]he Cotransformation process [claimed in the '216 patent] permit[s] the ... amplification of the gene of interest for the purpose of expressing large amounts of the protein it encoded."

127. In prosecuting the '275 patent, by contrast, Columbia characterized the claims of the '216 patent far more narrowly. For example, as set forth above, Columbia stated, in June 14,

2001 and January 30, 2002 responses to office actions, that "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." Columbia also stated that "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." These statements were made to avoid obviousness-type double-patenting rejections over the '216 patent and were meant to persuade the examiner to read the '216 patent's claims with a narrow scope.

128. Thus, Columbia's assertions to Congress of the sweeping breadth of the '216 patent directly contradict its exhortations to the examiner of the '275 patent to read the '216 patent narrowly. Columbia never disclosed its statements to Congress to the Patent Office or advised the examiner that it had ever taken contrary positions as to the scope of the '216 claims. It may reasonably be inferred from these facts that Columbia's omission to disclose these inconsistent statements to the Patent Office was deliberately misleading. The '275 patent is therefore unenforceable for inequitable conduct.

Count VII: Declaration of Unenforceability Due to Patent Misuse

129. Plaintiffs incorporate all prior paragraphs of this complaint.

130. The '275 patent is invalid and unenforceable.

131. Plaintiffs are entitled to and seek a declaratory judgment that the '275 patent is unenforceable by reason of patent misuse because Columbia has impermissibly sought to extend the economic benefit of its patent estate beyond its permissible scope. Among other things, Columbia has demanded royalty payments beyond the legitimate scope of its patent rights, enforced a patent it knew or had reason to know was invalid, manipulated the patent process and court proceedings to postpone indefinitely court consideration of the validity and enforceability of its patent, and attempted to monopolize intellectual property that should have entered the public domain in 2000.

132. There is an actual controversy between plaintiffs and Columbia concerning the unenforceability of the '275 patent.

Count VIII: Declaration of Exceptional Case

133. Plaintiffs incorporate all prior paragraphs of this complaint.

134. Plaintiffs are entitled to and seek a declaratory judgment that this is an exceptional case under 35 U.S.C. § 285 and that they are entitled to an award of reasonable attorneys' fees, costs, and expenses.

Requests for Relief

For the reasons set forth above, and for such other reasons that may be presented at trial, plaintiffs seek the following relief:

A. Judgment for plaintiffs against Columbia on all counts of this complaint;

B. Declarations of invalidity and unenforceability of the '275 patent on the grounds set forth above;

C. Declarations that Biogen and Genzyme are entitled to the more favorable royalty rates granted to other licensees;

D. Disclosure of all licenses of the Axel patents to Biogen and Genzyme;

E. Actual damages in favor of plaintiffs and against Columbia;

F. Treble damages for Columbia's knowing and willful violations of Mass. Gen. Laws c. 93A § 11;

G. A declaration that this is an exceptional case under 35 U.S.C. § 285;

H. An award of reasonable attorneys' fees, costs, and expenses; and

I. Such other or further relief that the Court deems just.

Dated: December 15, 2004

BIOGEN IDEC INC., BIOGEN IDEC MA INC. and GENZYME CORPORATION

By their attorneys,

/s/ Donald R. Ware

Donald R. Ware BBO # 516260
Claire Laporte BBO # 554979
Carla Miriam Levy BBO # 654212
Eva Ogielska Zei BBO # 655501
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210-2600
(617) 832-1000